SECOND SUPPLEMENTAL DECLARATION OF LARRY D. SASICH, PHARMD, MPH, FASHP

December 2, 2013

I was provided with additional documents that were filed in court by parties affiliated with the State of Missouri, for review on behalf of death-sentenced prisoners who are plaintiffs in the case of Zink et al. v. Lombardi et al. The documents are six pages in length and include three items labeled as "Certificate of Analysis" and one item labeled as a "Microbiology Report."

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This document is labeled as a "Certificate of Analysis" for Pentobarbital Sodium 50 mg/ml solution. Two 10 ml syringes containing 5 ml each were apparently provided for testing. The report does not indicate if the contents of the two syringes were from the same batch of pentobarbital sodium solution.

The analysis was conducted on November 8, 2013. The result was reported as pentobarbital sodium in a concentration of 50.490 mg/ml. It is not known if only one or both syringes were tested.

The name and the qualifications of the laboratory doing the analyses are unknown.

This Certificate of Analysis carries the following statement "The analyses referenced in this report are for [illegible word, I think it could be non] cGMP purposes only. The method(s) used for testing are not validated."

My interpretation of the above statement is that this laboratory's testing procedure cannot be used to indicate that the final product was produced under FDA current GMP guidelines. Additionally, the testing methods used were not validated.

This document is labeled as a "Microbiology Report" for pentobarbital sodium 50 mg/ml solution. Two 10 ml syringes containing 5 ml each were apparently provided for testing. It is not known if the contents of the two syringes are from the same or different lots.

The analysis was reported as "preliminary" with no growth reported at 7 days. The two syringes were received on November 7, 2013 and also tested on the same. The date that the pentobarbital sodium solution was produced is unknown and I have no explanation how a result of no growth at 7 days can be reported.

Under the box in which the results of the analysis are reported there are several statements in small print. The first statement is:

> "MB1-144 is listed as the sterility test method due to sampling not being performed per USP <71> guidelines and/or method suitability cannot be traced to your specific formulation."

I was unable to find information on the MB1-144 test method. USP <71> is the USP Chapter on Sterility Testing. I am unsure of the meaning of the rest of this statement.

This document if labeled as a "Certificate of Analysis" for a sample of pentobarbital sodium USP Active Pharmaceutical Ingredient (API). A handwritten note in the upper right corner indicates that 1.5794 grams were used.

The source of the API is unknown, as is the name and qualifications of the laboratory that did the test.

The lot number is redacted, as is the molecular weight (MW) of the product tested. The MW helps identify the chemical that is being tested.

At the bottom of the document the following statement appears:

> "The above test results have been obtained by our supplier or in our quality control laboratory. This analysis is not to be construed as a warranty, expressed or implied."

My interpretation is that this laboratory does not guarantee that the API tested was pentobarbital sodium USP.

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This document is page 2 of 2 of the "Certificate Of Analysis" of pentobarbital sodium USP described above.

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This document if labeled as a "Certificate of Analysis" for a sample of pentobarbital sodium USP Active Pharmaceutical Ingredient (API). A handwritten note in the upper right corner indicates that 8.9521 grams were used.

At the bottom of the document the following statement appears:

> "The above test results have been obtained by our supplier or in our quality control laboratory. This analysis is not to be construed as a warranty, expressed or implied."

My interpretation is that this laboratory does not guarantee that the API tested was pentobarbital sodium USP.

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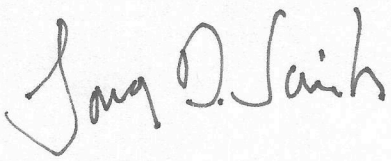
This document is page 2 of 2 of the "Certificate Of Analysis" of pentobarbital sodium USP described above.

I certify that the statements made above are accurate and true under penalty of perjury.



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